Docket: 1876
(203-1834)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Scott E. Manzo
Peter W.J. Hinchliffe
Kevin Sniffin

Serial No: To Be Assigned Examiner: Unknown

Filed: Concurrently Herewith Group Art Unit: Unknown

For: GRAFT ATTACHMENT ASSEMBLY

APPLICATION TRANSMITTAL LETTER

Asst. Commissioner For Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the [x] utility [ ] design patent application in this case including:

1. [ ] This application is a [ ] Continuation; [ ] Divisional [ ] Continuation in Part of prior application Serial No. _____ filed on _____ [entire genealogy should be set forth].

2. [ ] This application claims priority from Provisional Application No. _____, filed _____.

3. [X] The application consisting of 11 pages (including specification, claims and abstract).

4. [X] 3 sheet(s) of drawings is enclosed. The drawings are:

   a. [ ] formal; or
   b. [X] informal; formal drawings will be submitted in due course.

5. [X] A signed declaration and power of attorney is enclosed.

6. [ ] A declaration and power of attorney is not enclosed at this time since it has not been executed by the inventor(s). A signed declaration and power of attorney will be submitted in due course.
   The inventor(s) is/are _____.

7. [X] An Assignment of the invention to United States Surgical Corporation is enclosed. Please record the Assignment and return it to the undersigned. **TWO DUPLICATE COPIES OF THIS PAPER ARE ENCLOSED.**

8. [X] The Application filing fee is calculated below.

	No. Filed			No. Extra*	Rate:	Fee
Basic Fee:						$ 770.00
Total Claims:	25	- 20	=	5	x 22.00	$ 110.00
Indep Claims:	4	- 3	=	1	x 80.00	$ 80.00
[ ] Multiple Dependent Claims Presented				+ $260.00		$ 0.00
					TOTAL:	**$ 960.00**

9. [X] Please charge Deposit Account No. 21-0550 in the amount of $1,000.00 which includes filing fee and recordation fee). **TWO DUPLICATE COPIES OF THIS PAPER ARE ENCLOSED.**

10. [x] The Commissioner is hereby authorized to charge any additional fees which may be required for this application, or credit any overpayment to Deposit Account No. 21-0550. **TWO DUPLICATE COPIES OF THIS SHEET ARE ENCLOSED.**

Respectfully submitted,

Date: 3/13/97

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Serial No:	To Be Assigned	Examiner:	Unknown
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For:	**GRAFT ATTACHMENT ASSEMBLY**		

CERTIFICATE OF EXPRESS MAILING

"Express Mail" Mailing Label No.: IB701309741 US
Date of Deposit: March 13, 1997

I hereby certify that the following:

[x] This Certificate of Express Mailing
[x] Application Transmittal letter
[x] A patent application consisting of 11 pages of abstract, specification and claims
[x] Declaration and Power of Attorney for patent application [x] executed [ ] unexecuted
[x] 4 sheets of [ ] formal [x] informal drawings
[x] Assignment [x] executed [ ] unexecuted
[x] Assignment Recordation Sheet
[x] Return postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR Section 1.10 on the Date of Deposit indicated above in an envelope addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231.

Maureen M. O'Neill

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DOCKET: 1876
(203-1834)

GRAFT ATTACHMENT ASSEMBLY

BACKGROUND

1. Technical Field

The present disclosure relates generally to vascular grafts for surgical use and, more specifically, to a graft attachment assembly which may be easily and quickly assembled. The graft attachment assembly is particularly suited for vascular bypass surgical procedures.

2. Background of Related Art

Vascular grafts for use in surgical procedures for bypassing a section of a main artery to prepare the bypassed section of artery for surgical repair are well known and have taken a variety of different forms. Typically, vascular grafts include an inlet conduit to receive blood flow from an arterial source and an outlet conduit to deliver blood flow to a downstream location, e.g., same or different arteries, body organs, etc. A sealing device is positioned adjacent to each inlet and outlet conduit. Because of the nature of bypass procedures, it is important that a vascular graft be implantable in a relatively short period of time and that the vascular graft be properly attached to the vessels and adequately sealed at its inlet and outlet ends.

U.S. Patent No. 4,712,551 to Rayhanabad discloses a vascular shunt having a tubular inlet conduit and a plurality of outlet branch portions. The inlet conduit is configured to be received within an upstream arterial lumen and includes a sealing mechanism in the form of an expandable collar. Each outlet branch portion is configured to be received within a downstream arterial lumen and also includes an expandable collar. An air supply source communicates with each collar via an air supply line to inflate the collar and move the inlet conduit and each of the outlet branch portions into sealing engagement with the inner walls of the arterial lumen. Although the expandable seals might be

effective, the additional attachments required in the limited confines of a surgical site are undesirable.

U.S. Patent No. 5,156,619 to Ehrenfeld also discloses a vascular graft having a straight portion, and a flange portion including a crotch region. The flange portion is in the shape of a continuous flow curve and includes a suturing surface. The vascular graft is attached to the aorta using hand applied sutures. Ehrenfeld's vascular graft still requires the time consuming and oftentimes difficult process of suturing.

Accordingly, a need exists for an improved vascular graft attachment apparatus that can be easily and quickly implanted, provides improved sealing, and can be easily and inexpensively manufactured.

SUMMARY

In accordance with the present disclosure, a graft attachment assembly is provided having body, a clamp member, and a locking member. The connecting member includes a base portion preferably having a concave top surface and at least one branch portion having a passageway therethrough projecting outwardly from the base portion. The clamp member is preferably formed with a convex bottom surface configured to sealingly engage the top surface of the base portion and has an opening dimensioned to slidably receive the branch portion. The clamp member is movable about the branch portion to a position adjacent the base portion to clamp tissue therebetween. The locking member, preferably in the form of a locking ring, is slidable about the branch portion and is dimensioned to secure a vessel thereabout. A sealing assembly, preferably in the form of a rib formed on one of the top and bottom surfaces and a channel aligned with the rib formed in the other of the top and bottom surfaces, provides a seal between the base portion and the clamp member in the clamped position of the graft attachment assembly. The branch portion, illustratively, has at least one annular ramped surface positioned thereabout which is dimensioned to retain the locking ring in position about the distal end of the branch portion.

In a preferred embodiment, the clamp member is formed with at least one flexible retaining member positioned about the opening and the branch portion is formed with at least one row of teeth which is aligned with the at least one retaining member in the

clamped position to retain the clamp member in the clamped position adjacent the base portion. The retaining member is selectively movable into engagement with any one of the teeth in the row of teeth to accommodate tissues of different thicknesses. Advantageously, a branch portion of the graft attachment assembly may be attached directly to the target body vessel and thus itself serve as a graft or, the branch portion may be attached to an intermediary vascular of synthetic graft and serve as an attachment (connecting) member for the graft.

DETAILED DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view with parts separated of one embodiment of the vascular graft attachment assembly;

FIG. 2 is a side partial cross-sectional view of the graft attachment assembly shown in FIG. 1 in an assembled condition;

FIG. 3 is a cross-sectional view taken along section line 3-3 of FIG. 2;

FIG. 4 is a perspective view of the graft assembly shown in FIG. 1 implanted in the aorta; and

FIG. 5 is a perspective view of an alternate embodiment of the vascular graft attachment assembly.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed graft attachment assembly will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

FIGS. 1 illustrates one embodiment of the presently disclosed graft attachment (connecting) assembly shown generally as 10. Briefly, graft attachment assembly 10 includes an attachment (connecting) member or body 12, a clamp member 14, and a locking member 16. Each member of the three part assembly is preferably molded from a biologically compatible material, such as polytetrafluroethylene, although other suitable methods and materials which meet the requisite requirements for a vascular graft,

may also be used. The attachment assembly 10 is utilized to attach a vascular graft, other body tissue graft, or a synthetic graft to a vessel without requiring sutures. Attachment assembly 10 may also be used to attach one body vessel to a target body vessel and thereby serves as a graft itself.

Referring also to FIGS. 2 and 3, attachment member 12 is constructed with a base portion 18 having a convex top surface 20 configured to sealingly engage the interior wall of an arterial lumen. An annular rib 23 extends about the periphery of top surface 28. A tubular branch portion 24 defining a cylindrical passageway 21 extends outwardly from top surface 20 and is provided with at least one annular ramped surface 26 and at least one row of vertically aligned teeth 28. Illustratively, branch portion 24 is provided with two spaced annular ramped surfaces and four rows of vertically aligned teeth 28 spaced evenly about the periphery of branch portion 24, although other configurations may be used. Locking member 16, which is preferably a locking ring, is dimensioned to be slidably received about tubular branch portion 24, and will be described in detail below.

Clamp member 14 has a body 30 having a concave bottom surface 32 configured to sealingly engage top surface 20 of base portion 18. An opening 34 dimensioned to receive tubular branch portion 24 of attachment member 12 is formed in body 30. A plurality of diametrically opposed flexible retaining members 36 define a portion of opening 34 and are positioned to engage rows of vertically aligned teeth 28 formed on the outer periphery of tubular branch portion 28. Preferably, a retaining member 36 is provided for each respective row of teeth 28. An annular channel 38 is formed in bottom surface 32 of clamp member 14 and is positioned to receive rib 23 of attachment member 12 when the clamp member 14 is fastened to base member 12 in a clamped position.

Referring now to FIGS. 2-4, implantation of graft attachment assembly will now be described, by way of example, for use during a typical bypass procedure. It should be understood however, that the use of the attachment assembly in other procedures and for other vessels is contemplated. An incision is made in aorta 40 and base portion 18 of attachment member 12 is inserted through the incision. Attachment member 12 is positioned such that branch portion 24 projects through the incision and top surface 20 of base portion 18 is in contact with the inner wall of aorta 40. Clamp member 14 is pressed

downwardly onto attachment member 12 by sliding opening 34 of clamp member 14 about branch portion 24 to clamp tissue between bottom surface 32 of clamp member 14 and top surface 20 of base portion 18. Rib 23 forces tissue into channel 38 to provide a seal between clamp member 14 and attachment member 12. Clamp member 14 is retained in a clamped position by retaining members 36 which engage teeth 28. By providing multiple teeth in each row of teeth 28, the location of clamp member 14 with respect to base member 12 may be adjusted to accommodate tissues having different thicknesses. After attachment member 12 is securely fastened to aorta 40, a vessel 44, e.g., the saphenous vein, may be fastened to branch portion 24 by positioning locking ring 16 about a portion of the vessel 44 adjacent its exposed end, positioning vessel 44 about the distal end of branch portion 24, and sliding locking ring 16 about vessel 44 and branch portion 24 over the distal-most annular ramped surface 26 to a position between ramped surfaces 26. Locking ring 16 is constructed of a resilient material capable of passing over ramped surface 26 and compressing vessel 44 into sealing engagement with branch portion 24. Although branch portion 24 is shown oriented at a forty-five degree angle with respect to the longitudinal axis of attachment member 12, branch portion 24 may be oriented at any angle or direction suitable for the particular surgical application. Moreover, since graft attachment assembly 10 is easily removable by sliding locking ring 16 off the ramped surface 26, withdrawing the vessel from branch portion 24, and removing clamp member 14, it may be used for permanent or temporary applications.

FIG. 5 illustrates an alternate embodiment of the graft attachment assembly shown generally as 100. Graft attachment assembly 100 includes first, second, and third tubular branch portions 124a, 124b and 124c. Each branch portion has a pair of ramped surfaces 126 and at least one row of vertically aligned teeth 128a, 128b, and 128c. Clamp member 114 has three openings. Each opening is aligned with a respective branch portion and dimensioned to permit passage of the respective branch portion through the opening. Flexible retaining members 136a, 136b, and 136c define a portion of each opening and are engageable with the rows of teeth 128a-c to retain clamp member 114 in a clamped position fastened on attachment member 112. Although not illustrated, a locking member similar to locking ring 16 is associated with each branch portion 124a-c to sealingly fasten vasculature to the distal end of the respective branch portion. In the manner described

above, the locking ring would initially be placed adjacent the exposed end of the vessel, each vessel would be positioned over its respective branch, and each locking member would be moved to the ramped surface to frictionally engage the vessel to retain it on the branch.

It will be understood that various modifications may be made to the embodiments disclosed herein. As is apparent, any number of tubular branches can be provided to extend from graft member 12. Each branch can be placed at not only a 45° or 90° angle as shown, but can be placed at a variety of angles. Moreover, the tubular branches, on each graft member can be placed at different angles. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A graft attachment assembly comprising:

a body including a base portion having a top surface and a branch portion having a passageway therethrough projecting outwardly from the top surface of the base portion; and

a clamp member having an opening configured to receive the branch portion, the clamp member being movable about the branch portion, wherein the bottom surface of the clamp member may be positioned adjacent to the top surface of the graft member to clamp tissue therebetween.

2. A graft attachment assembly according to claim 1, wherein the top surface of the base member is convex and the bottom surface of the clamp member is concave.

3. A graft attachment assembly according to claim 2, further including a sealing assembly between the top and bottom surfaces.

4. A graft attachment assembly according to claim 3, wherein the sealing assembly includes a rib formed on one of the top and bottom surfaces and a channel formed in the other of the top and bottom surfaces, the rib being aligned with the channel in a clamped position.

5. A graft attachment assembly according to claim 1, further comprising a locking ring dimensioned to be received about the branch portion to retain tissue thereabout.

6. A graft attachment assembly according to claim 5, wherein the branch portion includes at least one annular ramped surface positioned thereabout and the locking ring is flexible, the ramped surface being dimensioned to retain the locking ring in position about the branch portion.

7. A graft attachment assembly according to claim 1, wherein the clamp member includes at least one retaining member positioned about the opening and, the branch portion includes at least one tooth which is aligned with the at least one retaining member in a clamped position, wherein the retaining member is movable into engagement with the at least one tooth to retain the clamp member in the clamped position.

8. A graft attachment assembly according to claim 7, wherein the at least one tooth includes a plurality of teeth, the retaining member being selectively movable into engagement with any one of the teeth to accommodate tissues of different thicknesses.

9. A graft attachment assembly comprising:

a graft member including a base portion having a top surface and a branch portion having a passageway therethrough, the branch portion projecting outwardly from the base portion;

a clamp member having a bottom surface configured to sealingly engage the top surface of the base portion and an opening dimensioned to slidably receive the branch portion, the clamp member being movable about the branch portion to a position adjacent to the base portion to clamp tissue therebetween; and

a locking member slidable about the branch portion, the locking member being dimensioned to secure a vessel about the branch portion.

10. A graft attachment assembly according to claim 9, wherein the top surface of the base member is convex and the bottom surface of the clamp member is concave.

11. A graft attachment assembly according to claim 10, further including a sealing assembly between the top and bottom surfaces.

12. A graft attachment assembly according to claim 11, wherein the sealing assembly includes a rib formed on one of the top and bottom surfaces and a channel formed in the other of the top and bottom surfaces, the rib being aligned with the channel in the clamped position.

13. A graft attachment assembly according to claim 12, wherein the branch portion includes at least one annular ramped surface positioned thereabout, the ramped surface being dimensioned to retain the locking ring in position about the branch portion.

14. A graft attachment assembly according to claim 13, wherein the clamp member includes at least one retaining member positioned about the opening and, the branch portion includes at least tooth which is aligned with the at least one retaining member in the clamped position, wherein the retaining member is movable into engagement with the at least one tooth to retain the clamp member in the clamped position.

15. A graft attachment assembly according to claim 14, wherein the at least one tooth includes a plurality of teeth, the retaining member being selectively movable into engagement with any one of the teeth to accommodate tissues of different thicknesses.

16. A graft attachment assembly according to claim 9, wherein the graft assembly is constructed from a biologically compatible material.

17. A graft attachment assembly according to claim 16, wherein the biologically compatible material is polytetrafluroethylene.

18. A graft attachment assembly comprising:

a base insertable into a vessel lumen, the base including at least one branch extending therefrom to receive a graft and a locking member positionable about the graft and mountable with respect to the branch to retain the graft on the branch.

19. A graft attachment assembly according to claim 18, wherein the locking member is a locking ring which presses the graft against the branch.

20. A graft attachment assembly according to claim 19, wherein the locking ring is slidable with respect to the branch.

21. A method of attaching a first and second vessel portions comprising the steps of:

(a) placing a base portion of a graft attachment assembly within a lumen of the first vessel portion, the graft attachment assembly including a branch portion projecting from the base portion, the branch portion being positioned to extend from the vessel;

(b) positioning a second vessel portion about a first end of the branch portion; and

(c) frictionally securing the second vessel portion about the branch portion.

22. A method according to claim 21 further comprising the step of clamping the base portion of the graft attachment assembly to the first vessel portion.

23. A method according to claim 21 further comprising the step of locking the base portion of the graft attachment assembly in the clamped position with respect to the first vessel portion.

24. A method according to claim 21, wherein the second vessel portion is a synthetic graft.

25. A method according to claim 21, wherein the first and second vessel portions are portions of discrete vessels.

ABSTRACT

A graft attachment assembly that may be easily and quickly assembled is provided. The graft attachment assembly includes an attachment member including a base portion having a convex top surface and a branch portion having a passageway therethrough. The branch portion projects outwardly from the base portion. A clamp member having a concave bottom surface is configured to sealingly engage the top surface of the base portion and an opening is dimensioned to slidably receive the branch portion. The clamp member is slidable about the branch portion to a position adjacent the base portion to clamp tissue therebetween. A locking member is slidable about the branch portion and dimensioned to secure a vessel thereabout.

FIG. 1

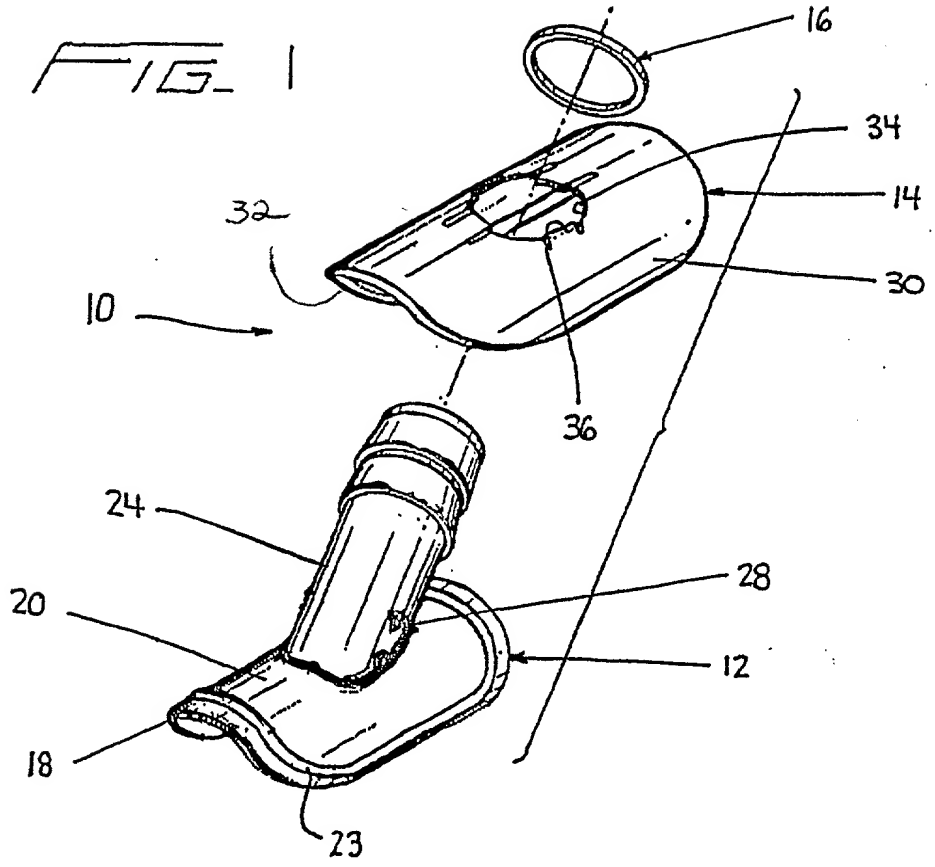
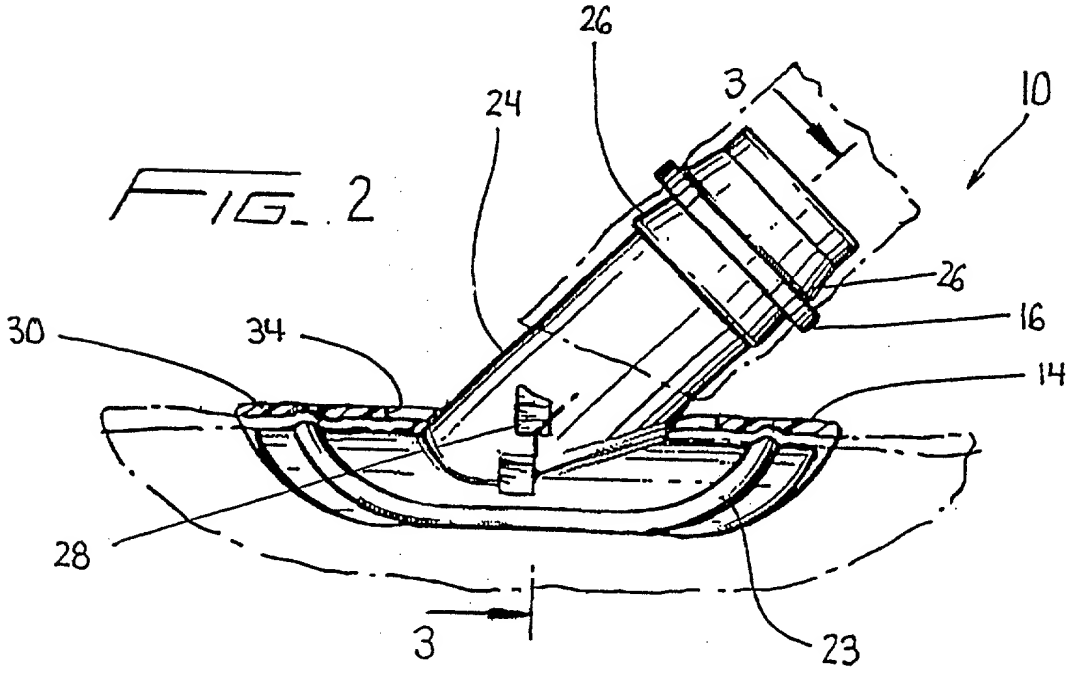


FIG. 2



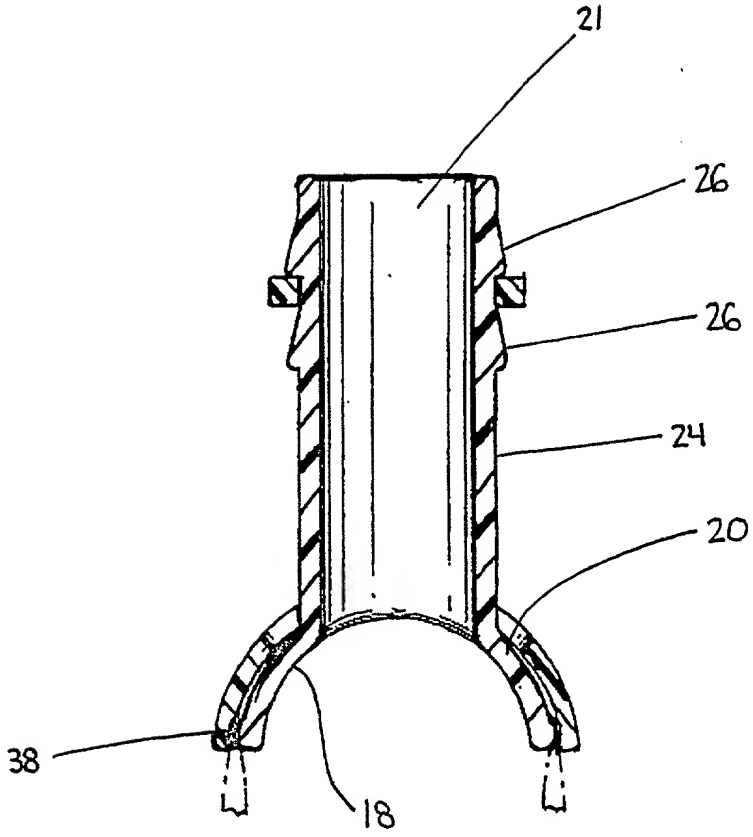
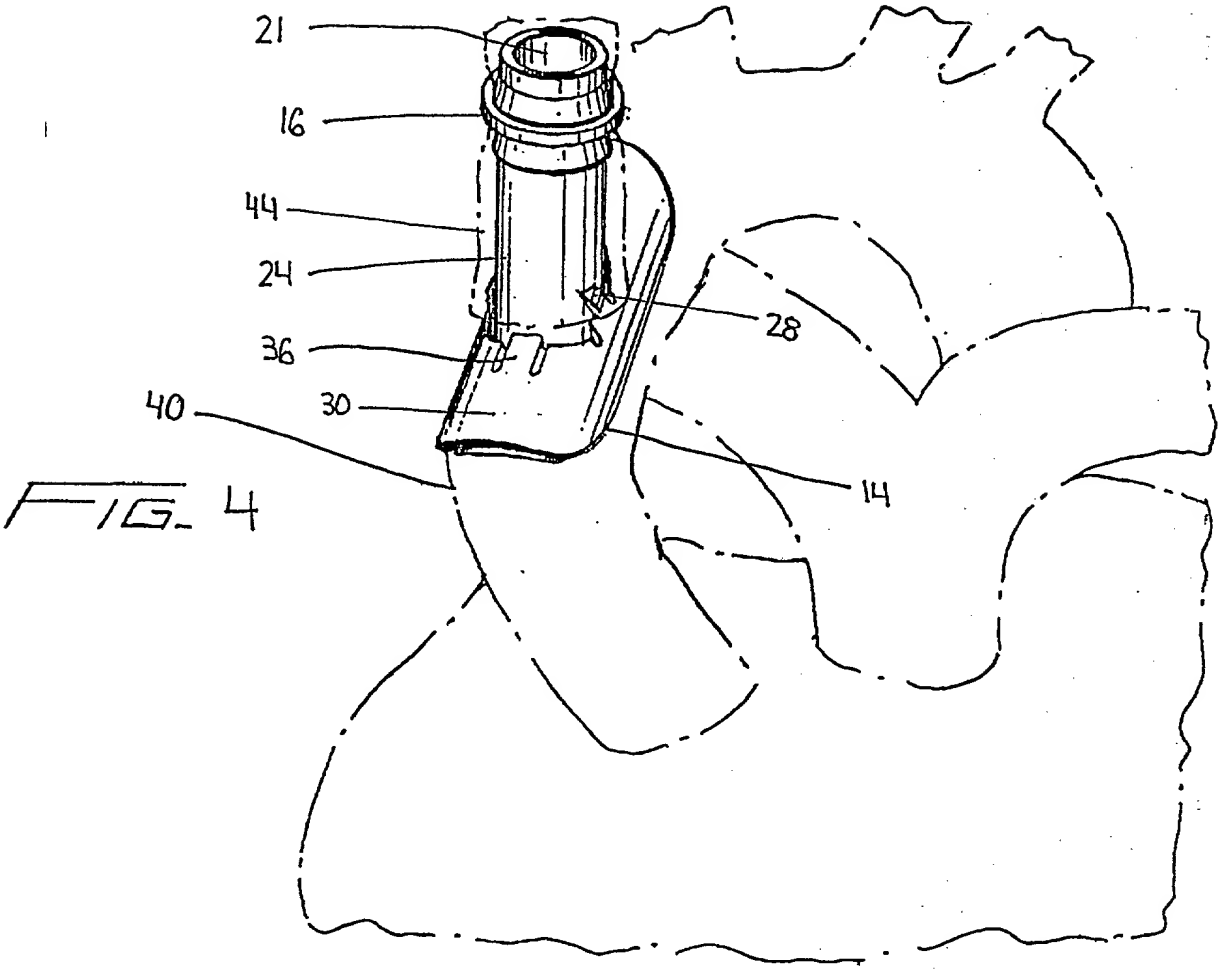


FIG. 3


21
16
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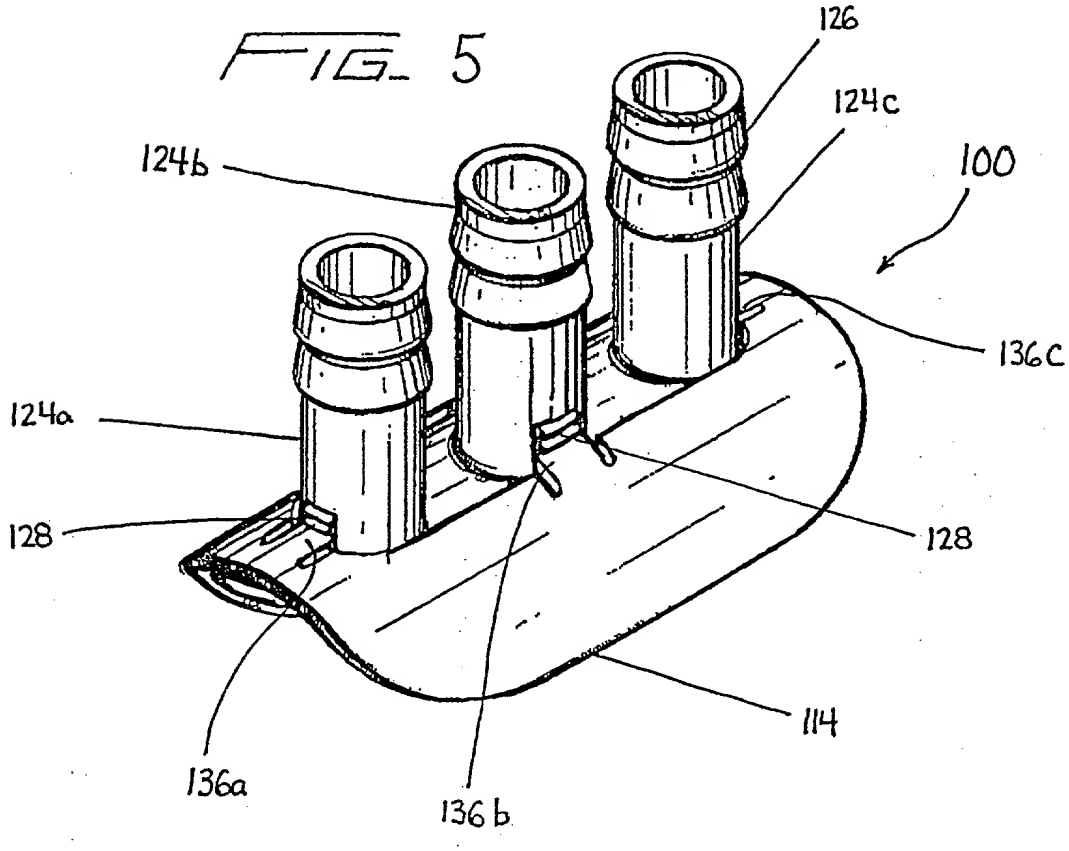
14

FIG. 4

FIG. 5


126
124c
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136c
124a
128
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114
136a
136b

Docket No. 1876
(203-1834)

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one)

[X] original
[ ] design

(check one, if applicable)
[ ] national stage of PCT
[ ] supplemental

[ ] divisional
[ ] continuation
[ ] continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

GRAFT ATTACHMENT ASSEMBLY

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b) or (c))

(a) [X] is attached hereto.
(b) [ ] was filed on _____ as [ ] Serial No._____.
or [ ] Express Mail No., as Serial No. not yet known.
and was amended _____ (if applicable).
(c) [ ] was described and claimed in PCT International Application No._____ filed on _____and as amended under PCT Article 19 on_____ (if any).

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

FOREIGN PRIORITY CLAIM

[ ] I hereby claim foreign priority benefits under Title 35, U.S.C. §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) [X] no such applications have been filed.
(e) [ ] such applications have been filed as follows

EARLIEST FOREIGN APPLICATIONS(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

COUNTRY	APPLICATION NO.	DATE OF FILING (month, day, year)	PRIORITY CLAIMED UNDER 35 USC 119
			[ ] YES [ ] NO

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. §120

[ ] I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in those prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §120, I acknowledge the duty to disclose material information as defined in 37 C.F.R. §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

Prior U.S. Application(s) or PCT International Application(s) Designating the U.S. For Benefit Under 35 U.S.C. §120.

U.S. APPLICATIONS

Serial No.	Filing Date	Status (issued, pending or abandoned)

PCT APPLICATIONS DESIGNATING THE U.S.

PCT Application No.	PCT filing date	U.S. Serial Nos. assigned (if any)	Status (patented, pending, abandoned)

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

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Direct Telephone Calls To:
(Name and telephone number)

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

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Inventor's signature P. Hinchliffe
Date 3/10/97 Country of Citizenship U.K.
Residence 285 Central Avenue, New Haven, Connecticut 06515
Post Office Address (same as above)

[x] Check here for added signature pages for third and subsequent inventors.
Number of added pages is 1.

Full name of third inventor **Kevin Sniffin**

Inventor's signature Kevin Sniffin

Date 3/10/97 Country of Citizenship U.S.A.

Residence 38 Grand Street, Danbury, Connecticut 06810

Post Office Address (same as above)